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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,682	05/09/2006	Yohei Okada	03327.2346	3661
22852 7590 04/02/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER EBRAHIM, NABILA G	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/02/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/578,682	Applicant(s) OKADA ET AL.	
	Examiner Nabila G. Ebrahim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, and 7 rejected under 35 U.S.C. 102(b) as being anticipated by M. Suzuki et al. Effects of (-)-S-2,8-dimethyl-3-methylene-1-oxa-8-azaspiro[4,5]decane L-tartrate monohydrate (YM796), a novel muscarinic agonist, on disturbance of passive avoidance learning behavior in drug-treated and senescence-accelerated mice, Volume 275, Issue 2, pp. 728-736, 11/01/1995 (hereinafter Suzuki.)

As the title shows Suzuki teaches the effects of the compound taught in the instant claims. The reference discloses that the compound is a novel muscarinic agonist, and has an effect on disturbance of passive avoidance learning behavior in drug-treated and senescence-accelerated mice. Muscarinic action of the autonomic nervous system is well known to people skilled in the art (see the attached document that describes the muscarinic activity of the autonomic nervous system, page 3). One of these activities is having anti-drying effect on eyes and the mouth.

Note that the effects of the drug and its mechanism of action recited in claims 3, and 4 are inherent properties of the drug.

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2. Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukamoto Shin-Ichi WO 9220683 (hereinafter "Shin").

Shin teaches the compound (-)-(S)-2,8-Dimethyl-3-methylene-1-oxa-8-azaspiro[4,5]decane L-tartrate having a storage stability superior to that of other salts and being applicable as a medicine (abstract) and also has a selective affinity for the muscarinic acetylcholine receptor. The hydrochloride, fumarate, maleate and di-p-toluoyl-D-tartrate salts of the compound can be utilized in the treatment of diseases. Note that the "treatment of tear and salivary fluid drying" is the intent of use of the composition, which is not considered of weight in the patentability of the instant claims because the prior art composition would have been inherently able to achieve the same use with success. However, it is also noted that it is within the muscarinic agonist effect of the compound to enhance the secretion of lacrimal and salivary glands.

3. Claims 1, 3-7 rejected under 35 U.S.C. 102(b) as being anticipated by Brann et al. US 6528529 (hereinafter Brann).

Brann teaches compounds with activity on muscarinic receptors. Brann's compounds are the same as the instant application recitation (col. 9, lines 4-6) and discloses that the preparation can be sustained-release (col. 12, lines 61+) and that the unit dosage forms can be in the form of tablets, pills, capsules, powders, granules, elixirs, tinctures, syrups and emulsions, sterile parenteral solutions or suspensions, aerosol or liquid sprays, drops, ampoules, auto-injector devices or suppositories. Note that all these forms usually include carriers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over any Brann in view of any of Suzuki, or Shin.

Brann has been discussed above.

Brann is deficient in the sense that he did not disclose the tartrate salt of the compound.

Suzuki, and Shin disclosed the use of the L-tartrate required by claim 2.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce 2,8-dimethyl-3-methylene-1-oxa-8-azaspiro[4,5]decane in a sustained-release form to prolong the action of the compound

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on lacrimal and salivary glands as disclosed by Brann and produce its tartrate salt because Shin discloses that the L-tartrate has a superior storage stability (abstract).

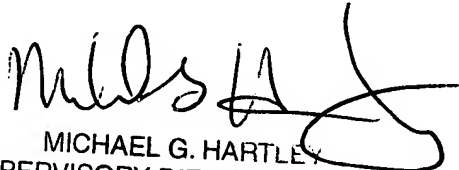
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
3/13/07


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER